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10/583,088	06/15/2006	Marie-Philippe Biron	P71338US0	1568

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,088	BIRON, MARIE-PHILIPPE	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4-7,12,21 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8-11,13-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of sequences with SEQ ID NO: 2, 3 and 8 in the reply filed on January 8, 2009 is acknowledged. The traversal is on the ground(s) that examiner should examine all other claims which do not directly read on the elected sequences. All of the claims reading on the elected sequences will be examined.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-7, 12, 21 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected sequences, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 8, 2009.

3. Claims 1-3, 8-11, 13-20 and 22-25 will be examined to the degree that they read on the elected sequences with SEQ ID NO: 2, 3 and 8.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on August 8, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Interpretation

5. Applicants defined the term "oligonucleotide" as follows (page 3, lines 10-12):

"As used herein, the term *"oligonucleotide"* refers to a nucleic acid sequence, which can be used as primer in an amplification procedure or as probe in a method of detection." No limit of the length is provided within this statement; therefore the term is interpreted as any nucleic acid.

6. The term "oligonucleotide includes a sequence" is interpreted as "oligonucleotide comprising a sequence".

7. Applicants did not define the term "complementary sequence", therefore any dinucleotide is considered to anticipate this term.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 8, 9, 11, 13-20 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the

particularly named SEQ ID NOs 1-12. Thus, applicant has express possession of only twelve particular oligonucleotides, in a genus which comprises millions of billions of different possibilities. Specifically, the claims are drawn to oligonucleotides comprising SEQ ID NO: 2, 3 or 8. Applicants' preferable length for oligonucleotides is less than 100 bp. Let us consider how many 100 bp sequences comprising SEQ ID NO: 2 there are. SEQ ID NO: 2 has 18 bp, therefore any 100mer would have 82 undefined nucleotides. Consequently, there would be 4^{82}, or $2.3x\ 10^{49}$ such sequences of 100 bp comprising SEQ ID NO: 2. The total number of oligonucleotides is much larger, since the the oligonucleotide can have any number of base pairs. Further, Applicants claim sequences complementary to SEQ ID NO: 2, 3 and 8. The term "complementary" has not been defined as a full complement, therefore any dinucleotide is complementary to any of the claimed sequences. Again, there are billions of nucleic acids comprising dinucleotides complementary to SEQ ID NO: 2, 3 or 8.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the oligonucleotide comprising SEQ ID NO: 2 lack any specific structure, and is precisely the situation of naming a type of material which is generally

known to likely exist, but, except for the twelve specific oligonucleotides, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to "an oligonucleotide comprising SEQ ID NO: 2", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as an oligonucleotide which can serve as a primer or a probe, without any definition of the particular sequences claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which consist of sequences with SEQ ID NO: 1-12. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 8-11 provide for the use of oligonucleotide with SEQ ID NO: 8, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 8-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-3, 8-11 and 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al. (J. Med. Virol., vol. 58, pp. 325-331, 1999) as evidenced by Heid et al. (Genome Res., vol. 6, pp. 986-994, 1996).

Regarding claims 1-3 and 13-16, Saito et al. teach a set of three oligonucleotides for the detection of the X gene of HBV (page 326, last paragraph). The first primer for the detection of the X gene comprises a sequence TCC (bp 17-19), which is complementary to bp 13-14 of SEQ ID NO: 2, for example. The second primer comprises bp 17-19, CTT, complementary to bp 16-18 of SEQ ID NO: 3. Finally, the probe sequence comprises nucleotides 14-16 CCT, complementary to bp 18-20 of SEQ ID NO: 8.

Regarding claims 8-11, Saito et al. teach the use of oligonucleotides to detect HBV (page 326, last paragraph; page 327, first paragraph).

Regarding claim 17, Saito et al. teach a method comprising:

a) contacting a set of oligonucleotides according to claim 13 with a biological sample or nucleic acid preparation obtained from a biological sample, under conditions suitable for the oligonucleotides to hybridize to a HBV nucleic acid present in the sample (page 326, last paragraph; page 327, first paragraph);

b) amplifying said HBV nucleic acid using said oligonucleotides as primers (page 326, last paragraph; page 327, first paragraph);

c) detecting the amplification product, indicative of the presence of a HBV in the biological sample (page 326, last paragraph; page 327, first paragraph).

Regarding claim 18, Saito et al. teach PCR (page 326, last paragraph).

Regarding claims 19 and 20, Saito et al. teach that the probes were TaqMan probes according to Heid et al. (page 325, second paragraph). As evidenced by Heid et al., TaqMan probes comprise a fluorophore and a quencher (page 987, second and third paragraph), anticipating the limitations of an oligonucleotide comprising a fluorophore and a quencher.

16. Claims 1-3, 8-11, 13-20 and 22-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Pasupuletti et al. (U.S. Patent No. 6,635,428 B2).

Regarding claims 1-3, 13-16, 22 and 25, Pasupuletti et al. teach a set of three oligonucleotides for the detection of HBV (col. 4, lines 48-65). The primer with SEQ ID NO: 1 comprises a sequence TCC (bp 6-8), which is complementary to bp 13-14 of SEQ ID NO: 2, for example. The primer with SEQ ID NO: 2 comprises bp 12-14, CGC, complementary to bp 14-16 of SEQ ID NO: 3. Finally, the probe with SEQ ID NO: 7 comprises nucleotides 2-5, CCTC, complementary to bp 17-20 of SEQ ID NO: 8.

Regarding claims 8-11, Pasupuletti et al. teach the use of oligonucleotides to detect HBV (col. 4, lines 48-65).

Regarding claim 17, Pasupuletti et al. teach a method comprising:

a) contacting a set of oligonucleotides according to claim 13 with a biological sample or nucleic acid preparation obtained from a biological sample, under conditions suitable for the oligonucleotides to hybridize to a HBV nucleic acid present in the sample (col. 4, lines 48-65);

b) amplifying said HBV nucleic acid using said oligonucleotides as primers (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61);

c) detecting the amplification product, indicative of the presence of a HBV in the biological sample (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61).

Regarding claim 18, Pasupuletti et al. teach PCR (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61).

Regarding claims 19 and 20, Pasupuletti et al. teach TaqMan probes labeled with a fluorophore and a quencher (col. col. 4, lines 48-65; col. 5, lines 10-28).

Regarding claims 22-25, Pasupuletti et al. teach kits for the PCR detection of HBV in real-time (col. 5, lines 64-67; col. 6, lines 1-9).

17. Claims 1-3, 8-11, 13-20 and 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Pasupuletti et al. (U.S. Patent No. 6,635,428 B2).

Regarding claims 1-3, 13-16, 22 and 25, Pasupuletti et al. teach a set of three oligonucleotides for the detection of HBV (col. 4, lines 48-65). The primer with SEQ ID NO: 1 comprises a sequence TCC (bp 6-8), which is complementary to bp 13-14 of SEQ ID NO: 2, for example. The primer with SEQ ID NO: 2 comprises bp 12-14, CGC, complementary to bp 14-16 of SEQ ID NO: 3. Finally, the probe with SEQ ID NO: 7 comprises nucleotides 2-5, CCTC, complementary to bp 17-20 of SEQ ID NO: 8.

Regarding claims 8-11, Pasupuletti et al. teach the use of oligonucleotides to detect HBV (col. 4, lines 48-65).

Regarding claim 17, Pasupuletti et al. teach a method comprising:

a) contacting a set of oligonucleotides according to claim 13 with a biological sample or nucleic acid preparation obtained from a biological sample, under conditions suitable for the oligonucleotides to hybridize to a HBV nucleic acid present in the sample (col. 4, lines 48-65);

b) amplifying said HBV nucleic acid using said oligonucleotides as primers (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61);

c) detecting the amplification product, indicative of the presence of a HBV in the biological sample (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61).

Regarding claim 18, Pasupuletti et al. teach PCR (col. 5, lines 10-28; col. 10, lines 66, 67; col. 11, lines 1-61).

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Regarding claims 22-25, Pasupuletti et al. teach kits for the PCR detection of HBV in real-time (col. 5, lines 64-67; col. 6, lines 1-9).

18. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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